K092322

Elecsys Rubella IgM Test system

MAR 12 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3723

Contact Person: Theresa A. Bush

Date prepared: March 12, 2010

Device Name

Proprietary name: (1) Elecsys Rubella IgM Immunoassay
(2) Elecsys Rubella IgM PreciControl

Common name: (1) Rubella IgM Immunoassay
(2) Rubella IgM PreciControl

Classification name: (1) Rubella Virus serological reagents
(2) Single (specified) analyte controls (assayed and unassayed)

Device Description

(1) The Elecsys Rubella IgM Immunoassay is a two-step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. The Rubella IgM is composed of a biotin-labeled monoclonal antibody against human IgM, a Rubella-like particle and a ruthenium-labeled anti-Rubella antibody. A relationship exists between the concentration of the IgM antibody targets present in a patient sample and the level of signal count detected by the system. The IgM assay is a qualitative test based on a cut-off formula dependent on the negative and positive calibrators. Cut-off index (COI) is based on the ratio of assay signal to cut-off signal (also abbreviated s/co). COI values equal to or greater than 1.0 are considered positive for the presence of anti-Rubella IgM antibody. Results are determined using a 2 point calibration. The test system contains the human serum-based calibrators intended for use with the system.
(2) The Elecsys PreciControl Rubella IgM contains two levels of human serum. The positive control contains native, inactivated Rubella IgM antibodies.

510(k) Summary, Continued

Intended use

(1) The Elecsys Rubella IgM immunoassay is for the *in vitro* qualitative determination of IgM antibodies to rubella virus in human serum and Li-heparin, K3-EDTA, and sodium citrate plasma. This assay may be used as an aid in the presumptive diagnosis of an acute or recent rubella infection in individuals, including women of childbearing age. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers. NOTE: This assay has not been cleared/approved by the FDA for blood/plasma donor screening.
(2) Elecsys PreciControl Rubella IgM is used for quality control of the Elecsys Rubella IgM immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Indications for Use

(1)The Elecsys Rubella IgM assay may be used as an aid in the presumptive diagnosis of an acute or recent rubella infection, particularly in women of childbearing age.

510(k) Summary, Continued

Substantial equivalence

The Elecsys Rubella IgM Test system is substantially equivalent to other devices legally marketed in the United States.

(1) Elecsys Rubella IgM Immunoassay is equivalent to the Zeus Scientific Rubella IgM ELISA Test System cleared in K984180
(2) Elecsys PreciControl Rubella IgM is equivalent to the Elecsys PreciControl TnT (K031990)

The devices are compared to their predicates in the tables below.

510(k) Summary, Continued

(1) Rubella IgM Immunoassay Comparison		
Feature	**Elecsys Rubella IgM Immunoassay**	**Predicate Device: Zeus Scientific Rubella IgM ELISA Test System (K984180)**
Intended Use	The Elecsys Rubella IgM immunoassay is for the *in vitro* qualitative determination of IgM antibodies to rubella virus in human serum and Li-heparin, K_3-EDTA and sodium citrate plasma. This assay may be used as an aid in the presumptive diagnosis of an acute or recent rubella infection, particularly in women of childbearing age. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers. Note: This assay has not been cleared/approved by the FDA for blood/plasma donor screening.	The Zeus Scientific, Inc. Laboratories Rubella IgM ELISA Test System is designed for the qualitative detection of IgM antibodies to rubella virus in human serum. The test system is intended to be used to evaluate serological evidence of acute or recent infection with rubella virus and is for in vitro diagnostic use
Indication for Use	aid in the presumptive diagnosis of an acute or recent rubella infection, particularly in women of childbearing age.	is intended to be used to evaluate serological evidence of acute or recent infection with rubella virus and is for in vitro diagnostic use
Assay Protocol	Electrochemiluminescent Immunoassay	ELISA
Sample Type	Human serum, lithium heparin plasma, potassium (K_3) EDTA plasma and sodium citrate plasma	Serum
Instrument Platform	Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) and **cobas e** immunoassay analyzers.	No automated instrument platform. ELISA equipment/ microwell plate reader needed. No specific model required.
Calibrator	Included in kit	Included in kit
Calibrator levels	Two	One
Format	Human serum	Human serum

Elecsys Rubella IgM Test system

Calibrator Stability	After opening at 2-8C: 8 weeks On Elecsys 2010/ cobas e 411: up to 5 hours On E170/ cobas e 601: use only once	Store between 2-8 °C.
Calibration frequency	Once per reagent lot and • After 1 month when using same reagent lot • After 7 days when using same reagent kit • As required per QC findings or pertinent regulations	Each time the assay is run.
Controls	PreciControl Rubella IgM (sold separately)	Positive and negative control included in kit.
Traceability	Roche standard with arbitrary units	Recovery of WHO Reference Standard is shown.
Reagent Stability	Unopened 2-8°C – up to expiration Opened 2-8°C – 12 weeks Onboard– 2 weeks or 12 weeks (stored alternately in refrigerator and on the analyzer- ambient temperature 20-25°C; up to 84 hours opened in total.)	Unopened kit: Store at 2-8°C. Coated microwell strips: 2-8°C should be immediately resealed with dessicant ; stable 60 days provided indicator on dessicant pouch remains blue. Conjugate, Control, Calibrator, TMB, and Diluent: 2-8°C Wash buffer and Stop Solution: 2-25°C Diluted wash buffer: stable at room temperature 7 days or 30 days at 2-8°C
Precision	Intrassay: (range of values) Low Control: CV 1.38 - 5.74% High Control: CV 1.14 – 4.83 % Plasma Samples: CV: 1.03 6.71% Inter-assay: Low Control: CV 2.04 – 10.52% High Control: CV 2.77 – 10.43 % Plasma Sample 1.86 – 17.07 % units	Intraassay: Negative: 27-60% Negative close to equivocal: 3.1-7.1% Equivocal: 1.2-10.1% High Positive: 3.4-9.3% Low Positive: 3.2-5.4% Inter-assay: Negative: 48% Negative close to equivocal: 16.4% Equivocal: 3.5% High Positive5.7% Low Positive: 4.1%
Analytical Specificity	77.6 % agreement with predicate for 60 specimens representing a variety of disease states.	Not stated.

wash buffer and stop solution

Elecsys Rubella IgM Test system

Interferences	The assay is unaffected by icterus (bilirubin < 428 µmol/L or < 25 mg/dL), hemolysis (Hb < 1.49 mmol/L or < 2.4 g/dL), lipemia (Intralipid < 1500 mg/dL), Immunoglobulin A up to 9.6 mg/mL. Immunoglobulin G up to 42 mg/mL and biotin < 205 nmol/L or < 50 ng/mL. Criterion: Recovery of positive samples within ± 20% of initial value. RF factor was not observed to cause any consistent bias, but RF factor levels higher than 1650 IU/mL may lead to erroneous results in some instances. Elevated levels of IgM may cause interference. There is no high dose hook effect up to a COI of 24.0. As with many µ-capture assays an interference with unspecific human IgM is observed. Increasing amounts of unspecific human IgM may lead to a decrease in the recovery of positive samples with the Elecsys Rubella IgM assay.	No anticoagulants or preservatives should be added; avoid using hemolyzed, lipemic, or bacterially contaminated samples. IgG antibody can cause false negative results. Epstein-Barr can cause false response, infectious mononucleosis and autoimmune disease can cause false positives.
Method Comparison (Elecsys vs Zeus Scientific/Abbott AxSym and DPC Immulite):	Pregnant Subjects: Negative Agreement: 99.20% (131/132) 95.90%-99.98% Positive Agreement: 0.00% (0/0) 0%-100% Non-Pregnant Subjects: Negative Agreement: 98.90% (364/368) 97.20-99.70% Positive Agreement: 0.00% (0/1) 0.00-97.5%	

(2) Precicontrol Comparison		
Feature	**Elecsys Precicontrol Rubella IgM**	**Predicate Elecsys Precicontrol Troponin T (K031990).**
Intended Use	Elecsys PreciControl Rubella IgM is used for quality control of the Elecsys Rubella IgM immunoassay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Troponin T is used for quality control of the Elecsys Troponin T (Cardiac T) immunoassay on the Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Levels	Two	Two
Matrix	Human serum	Human serum
Format	Ready to use	Lyophilized
Stability	Unopened: up to the stated expiration date After opening at 2-8C: 8 weeks Onboard: 5 hours	Unopened: up to the stated expiration date After reconstituting: at 2-8C: 2 weeks At -20C: 8 weeks Onboard: 5 hours

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

MAR 12 2010

Roche Diagnostics
c/o Theresa A Bush
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, IN, 46250-3831

Re: k092322

Trade/Device Name:	Elecsys Rubella IgM Immunoassay Elecsys PreciControl Rubella IgM
Regulation Number:	21CFR §866.3510
Regulation Name:	Rubella virus serological reagents
Regulatory Class:	Class II
Product Code:	LFX JJX
Dated:	March 5, 2010
Received:	March 9, 2010

Dear Ms. Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k092322

Device Name: Elecsys Rubella IgM Immunoassay

Indications for Use:

The Elecsys Rubella IgM immunoassay is for the *in vitro* qualitative determination of IgM antibodies to rubella virus in human serum and Li-heparin, K3-EDTA, and sodium citrate plasma. This assay may be used as an aid in the presumptive diagnosis of an acute or recent rubella infection in individuals, including women of childbearing age. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers. NOTE: This assay has not been cleared/approved by the FDA for blood/plasma donor screening.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Uwe Scherf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092322

Indications for Use Form

510(k) Number (if known): k092322

Device Name: PreciControl Rubella IgM

Elecsys PreciControl Rubella IgM is used for quality control of the Elecsys Rubella IgM immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Uwe Scherf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092322